



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,512	03/12/2004	Steven M. Ruben	PZ039P1C2	6667

22195 7590 03/22/2007
HUMAN GENOME SCIENCES INC.
INTELLECTUAL PROPERTY DEPT.
14200 SHADY GROVE ROAD
ROCKVILLE, MD 20850

EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
----------	--------------

1646

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/798,512

Applicant(s)

RUBEN ET AL.

Examiner

Dong Jiang

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 15 and 25-46 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 14, 15 and 25-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/22/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Applicant's election with traverse of Group II invention, represented by the original claims 11, 12 and 16, filed on 22 January 2007 is acknowledged. The traversal is on the ground(s) that, according to MPEP, even where two patentably distinct inventions appear in a single application, restriction remains improper unless it can be shown that the search and examination of both inventions would entail a serious burden, that applicants disagree that it would impose an undue burden to examine the nucleic acid, polypeptide, antibody, and method claims together, that to search and examine the subject matter of all the groups would not be a serious burden, and that a search of polynucleotide claims would provide useful information for examining claims directed to both polynucleotides and the polypeptides encoded thereby. This is not found persuasive because, first, there are ten distinct inventions in the instant application, not two. Further, according to MPEP, a serious burden may be established by (A) separate classification thereof; (B) a separate status in the art when they are classifiable together; or (C) a different field of search. In the instant case, Groups I-X are patentably distinct inventions as shown by their separate classification, indicating each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. As stated in the MPEP 803, "a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 802.02". Further, any search of the prior art in regard to one group will not necessarily reveal information related to the other groups. For example, a search of a polypeptide isolated from its natural source would not necessarily reveal information about the polynucleotide encoding the polypeptide. Additionally, a search is aimed to find references that would render the invention obvious, as well as references directed to anticipation of the invention. Therefore, a search for one group is not adequate as to revealing references anticipating the other groups even though it may provide *useful* information for the claims of the other groups. As such, all groups require independent and divergent searches, and to search all groups of inventions would constitute serious burden. Further, applicants have

Art Unit: 1646

canceled the non-elected claims 1-13 and 16-24, indicating that the traversal of the restriction requirement among the groups consisting of these claims is moot.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's amendment filed on 22 January 2007 is acknowledged and entered. Following the amendment, the original claims 1-13 and 16-24 are canceled, and the new claims 25-46 are added.

Currently, claims 14, 15 and 25-46 pending, and claims 25-46 are under consideration. Claims 14 and 15 are withdrawn from further consideration as being drawn to a non-elected invention.

Formal Matters:

Information Disclosure Statement

Applicant's IDS submitted on 1/22/07 is acknowledged and has been considered. A signed copy is attached hereto.

Priority acknowledgement

This application claims benefit of U.S. applications 10/050,704 and 09/684,524, PCT/US00/08979, and U.S. provisional application 60/128,693 and 60/130,991, which is acknowledged.

Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-46 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Art Unit: 1646

Claims 25-46 are directed to an isolated polypeptide having the amino acid sequence of SEQ ID NO:108, variants and fragments thereof, and composition thereof. Said polypeptide is encoded by a cDNA clone designated HSSGD52.

The specification discloses a polypeptide of HSSGD52 having an amino acid sequence of SEQ ID NO:108, which is encoded by the nucleic acid of SEQ ID NO:22. The specification discloses that said polypeptide shares sequence homology with a non-adrenergic smooth muscle binding protein, a membrane spanning receptor capable of binding iodocyanopindolol (ICYP) under blockade of adrenergic receptors and serotonin receptors (page 38, lines 24-28), and that this gene is expressed primarily in breast, activated monocytes, T-cells, placenta and infant brain, and is also expressed in a number of normal and cancerous tissues (page 39, lines 12-14). The specification asserts that, therefore, the polypeptides are useful to provide immunological probes for differential identification of the tissues or cell types (page 39, lines 18-20); and that the homology to a membrane receptor and tissue distribution suggests that this protein may play a role in the regulation of cellular division; in the proliferation, differentiation, and/or survival of hematopoietic cell lineages; and in the regulation of the immune response; and that it may also be involved in apoptosis or tissue differentiation and could be useful in cancer therapy, and for diagnosis and treatment of a number of diseases (pages 40-41).

The asserted utilities are not considered to be specific or substantial because they are merely based on the sequence homology and tissue distribution, and the specification fails to disclose any functional activity or biological significance directly associated with the polypeptide of SEQ ID NO:108. With respect to sequence homology, generally, the art acknowledges that function cannot be predicted based solely on structural similarity to a known protein. For example, in the transforming growth factor (TGF) family, Vukicevic et al. (1996, PNAS USA 93:9021-9026) disclose that OP-1, a member of the TGF- β family of proteins, has the ability to induce metanephrogenesis, whereas closely related TGF- β family members BMP-2 and TGF- β 1 had no effect on metanephrogenesis under identical conditions (page 9023, paragraph bridging columns 1-2). Additionally, IL-18 receptor (IL-18R) was thought to be another IL-1 receptor (IL-1R) base on the sequence homology, and therefore, designated IL-1 receptor-related protein (IL-1Rrp) when it was first discovered, and its ligand was unknown

Art Unit: 1646

(Parnet et al., J. Biol. Chem., 1996, 271(8): 3967-70). IL-1Rrp is now known as IL-18 receptor, has distinct ligand, and possesses distinct functional properties from that of IL-1R even though it is a member of IL-1R family. Therefore, established utilities for known proteins can not be automatically applied to the present HSSGD52 protein of SEQ ID NO:108 without functional analysis, and the specification fails to provide any line of direct evidence as to the functional property or biological significance of the protein. The disclosed uses in treatment of a number of diseases are not substantial in the absence of knowledge such as functional properties, biological significance, or any disease/disorder directly associated with the protein of SEQ ID NO:108, which could be so diagnosed or treated. While it is possible that the protein may be a member of a known receptor family, that by itself does not suggest a substantial utility for the reasons above.

With respect to the tissue distribution, as the HSSGD52 is expressed in a number of tissues/cell types, clearly, it is not suitable for differential identification of the tissues or cell types. Further, as the tissues/cells expressing the HSSGD52 would also concurrently express hundreds of other protein molecules with distinct functional properties, it is impossible that the specific functional activity or biological significance of a particular polypeptide can be predicted solely based on its tissue distribution.

Clearly the utility of the HSSGD52 protein of SEQ ID NO:108 requires additional knowledge about the molecule before it can be used for the asserted purposes (useful in cancer therapy, and for diagnosis and treatment of a number of diseases), and further research/experimentation is required in order to determine, for example, whether and how the protein of SEQ ID NO:108 is associated with any disease, so it can be used for diagnosis and therapy or as a target. As such, the claimed protein is not supported by a substantial utility because, according to MPEP, a **substantial utility** is a utility that defines “real world” use, and a utility that requires or constitutes carrying out further research to identify or reasonably confirm a “real world” context of use is not a substantial utility.

The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the

Art Unit: 1646

opinion that all chemical compounds are “useful” to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of “useful” as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed “real world” utility. The court held that:

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. ... a patent is not a hunting license. ... [i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are drawn to proteins of as yet undetermined function or biological significance. There is no evidence of record or any line of reasoning that would support a conclusion that said HSSGD52 protein of SEQ ID NO:108 was, as of the filing date, useful for diagnosis and treatment of any of the disorders stated at pages 40-41 of the specification. Until some actual and specific biological significance can be attributed to the polynucleotide or polypeptide identified in the specification as HSSGD52, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent or “real world” utility and the claimed invention is incomplete as of the filing date.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-46 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Art Unit: 1646

Claims 36-46 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 36 recites a deposit of a cDNA clone encoding said protein contained in ATCC Deposit No. PTA-1543. However, the specification fails to provide the deposit statement indicating the deposit material will be readily available to the public without restriction upon issuance of the patent. Such statement would satisfy the enablement requirement of 35 U.S.C. 112.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating

- (a) that the deposit has been made under the terms of the Budapest Treaty; **and**
 - (b) that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent,
- would satisfy the deposit requirements. See 37 C.F.R. 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then the requirements may be satisfied by an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or by a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and establishing that the following criteria have been met:

- (a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;
- (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;
- (c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- (d) a viability statement in accordance with the provisions of 37 C.F.R. 1.807 is provided; and

Art Unit: 1646

(e) the deposit will be replaced should it become necessary due to inviability, contamination, or loss of capability to function described in the manner in the specification.

In either case, the identifying information set forth in 37 C.F.R. 1.809(d) should be added to the specification if it is not already present. For deposits made with the ATCC, note that effective 23 March 1988 the depository's address is:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

See 37 C.F.R. 1.803-1.809 for additional explanation of these requirements.

Claims 25, 29-36 and 40-46 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a protein at least 90% or 95% identical to the amino acid sequence of SEQ ID NO:108 (claim 35, parts (d) and (e), for example), or to amino acid sequence encoded by the HSSGD52 cDNA (claim 36, parts (d) and (e), for example), or drawn to a fragment of the protein (parts (f) and (g) of claims 35 and 36, for example). The claims do not require that said polypeptides possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that are defined only by sequence identity. The specification merely discloses *one* polypeptide of SEQ ID NO:108, and no variants, or fragments thereof meeting the limitation of the claim were ever identified or particularly described.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factors present in the claim are a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved in the protein.

Art Unit: 1646

Therefore, the skilled artisan cannot envision the sequence structure of the encompassed protein variants and fragments. Further, the specification does not teach the functional property of the protein. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

With the exception of the polypeptide of SEQ ID NO:108, and that encoded by the the HSSGD52 cDNA, the skilled artisan cannot envision the detailed chemical structure of the encompassed protein variants. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the amino acid sequence set forth in SEQ ID NO:108, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. This is particularly important in absence of a specific known activity. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-37 and 44-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: how to express and how to recover said protein. Claim 46 is similarly indefinite.

Claim 36 is further indefinite for the recitation “the *secreted* portion of ...” (part (a), for example) because it is unclear as to what “*secreted* portion” refers, since the HSSGD52 protein of SEQ ID NO:108 is a membrane bound protein (page 39, lines 7-11).

The remaining claims are included in this rejection because it is dependent from the specifically mentioned claims without resolving the indefiniteness issue belonging thereto.]]

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-32, 34-43, 45 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Chluba-de Tapia et al. (Gene, 1997 Sep 15; 197(1-2):195-204, provided by applicants), and as evidenced by Nishimura et al. (US6,309,859).

Chluba-de Tapia discloses the sequences of a human multispinning membrane protein cDNA and the protein encoded thereby, named hMP70 (Figure 1), wherein in the amino acid sequence of hMP70 is 100% identical to the present SEQ ID NO:108 (see appended computer printout of sequence search result). As such, the reference anticipates claims 25-32 and 36-43. Note, with respect to claim 38, although Chluba-de Tapia does not explicitly mention the polypeptide without the N-terminal methionine, it is well known in the art that in naturally produced mature protein molecules, the N-terminal methionine is usually no longer present as it is removed via subsequent processing, which is evidenced by Nishimura (column 1, lines 19-22).

Art Unit: 1646

Thus, when Chluba-de Tapia's hMP70 polypeptide is isolated from a natural source, it would be the polypeptide without the N-terminal methionine.

With respect to claims 34 and 45, although Chluba-de Tapia does not explicitly teach a composition of the polypeptide and a pharmaceutically acceptable carrier, however, it is well known in the art that a purified protein is usually used (for research, for example) in combination with other agent(s), such as a dissolving solution. A dissolving solution, such as water, buffers, or media, meets the limitation of "a pharmaceutically acceptable carrier". A composition comprising Chluba-de Tapia's polypeptide dissolved in water or buffer is not patentably distinct from the polypeptide in the present claims because the polypeptide, as the effective ingredient, is the same, and thus, the reference anticipates the claims.

With respect to claims 35 and 46, the protein is claimed by the method of making. However, a claim limitation of product by process is given patentable weight only when the recited process alters or affects the nature of the product, for example, rubber made by the process of vulcanization is different from rubber made by other processes with respect to its strength. In the instant case, the claims do not recite any specific method steps indicating a difference between the presently claimed polypeptide and Chluba-de Tapia's hMP70 polypeptide. In the absence of evidence to the contrary, the preset claim limitation of the product by process is not given patentable weight. Thus, the reference anticipates claims 35 and 46.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 1646

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 33 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chluba-de Tapia et al. (Gene, 1997 Sep 15; 197(1-2):195-204) as applied to claims 25-32, 34-43, 45 and 46 above, and further in view of Capon et al. (US 5,116,964).

The teachings of the primary reference are summarized above. Additionally, Chluba-de Tapia teaches that hMP70 membrane protein shows no homology with GPCR or other families of transmembrane proteins (page 195, the paragraph bridging the two columns), that the mRNA of hMP70 is detectable in all human tissues analyzed, and that from its widespread expression and conservation from yeast, plants to mammals, it is likely that hMP70 has a fundamental biological function in the cell (abstract). Chluba-de Tapia does not specifically teach a fusion protein comprising said polypeptide and a heterologous polypeptide sequence.

Capon discloses a novel polypeptide comprising a ligand binding partner fused to moieties such as an immunoglobulin constant domains (Fc region, for example), and teaches that fusion of a target protein to a protein such as an immunoglobulin constant domain facilitates purification of the protein (column 4, lines 38-42, column 5, lines 13-20, and column 10, lines 12-16).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to make a fusion protein comprising the target protein as taught by Chluba-de Tapia, and an immunoglobulin Fc region following the teachings of Capon. One of ordinary skill in the art would have been motivated to make the Fc fusion protein because it would facilitate purification of the protein as taught by Capon, and therefore facilitate further research of the hMP70 protein as Chluba-de Tapia suggests that hMP70 has a fundamental biological function in the cell, and reasonably would have expected success in view of Capon's disclosure, in which various fusion proteins had already been made successfully using Capon's systems at the time the invention was made.

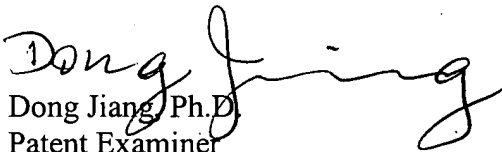
Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Dong Jiang, Ph.D.
Patent Examiner
AU1646
3/12/07